IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No.	: 10/552,660
Applicant	: Yan HONG
Filed	: October 11, 2005
TC/A.U.	: 1646
Examiner	:
Docket No.	: 2577-158
Customer No.	: 06449
Confirmation No.	: 1905

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

RESPONSE TO NOTICE TO COMPLY

Dear Sir:

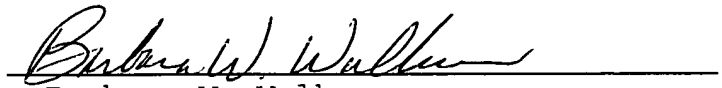
In response to the Notification to Comply with Requirements for Patent Applications Containing Nucleotide and/or Amino Acid Sequence Disclosures (copy herewith), enclosed please find a replacement copy of the "Sequence Listing" in computer readable form.

It is hereby certified that the sequence information contained in the computer readable copy is identical to the paper copy of the "Sequence Listing" in the application as filed. A paper copy of the "Sequence Listing" is also included with this paper.

The Notification to Comply with Requirements for Patent Applications Containing Nucleotide and/or Amino Acid Sequence Disclosures further asserts that additional claims fees of $50 are required for the application. As a first matter, the transmittal letter filed with the application referenced above authorized the Commissioner to charge any additional fees that may be required to respondent's deposit account. Thus, no further fees should have been required. However, a review of the

application as filed indicates that the application contains 21 claims, as was correctly indicated on the PTO Form 1390 transmittal letter. This paper provides a copy of the claims from the application as filed on October 11, 2005 and a copy of the PTO Form 1390.

Respectfully submitted,

By 

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UNITED STATES PATENT AND TRADEMARK OFFICE

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U.S. APPLICATION NUMBER NO.	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
10/552,660	Yan Hong	2577-158

INTERNATIONAL APPLICATION NO.	
PCT/SG04/00093	
I.A. FILING DATE	PRIORITY DATE
04/14/2004	04/14/2003

6449
ROTHWELL, FIGG, ERNST & MANBECK, P.C.
1425 K STREET, N.W.
SUITE 800
WASHINGTON, DC 20005

CONFIRMATION NO. 1905

371 FORMALITIES LETTER

OC000000019157262

Date Mailed: 06/08/2006

NOTIFICATION TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE AND/OR AMINO ACID SEQUENCE DISCLOSURES

Applicant is given **TWO MONTHS FROM THE DATE OF THIS NOTICE** within which to file the items indicated below to avoid abandonment. Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

The applicant needs to satisfy supplemental fees problems indicated below.

The following items **MUST** be furnished within the period set forth below in order to complete the requirements for acceptance under 35 U.S.C. 371:

- Additional claim fees of **$50** as a non-small entity, including any required multiple dependent claim fee, are required. Applicant must submit the additional claim fees or cancel the additional claims for which fees are due.

SUMMARY OF FEES DUE:

Total additional fees required for this application is **$50** for a Large Entity:

- A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 CFR 1.821(e). If the effective filing date is on or after September 8, 2000, see the final rulemaking notice published in the Federal Register at 65 FR 54604 (September 8, 2000) and 1238 OG 145 (September 19, 2000). Applicant must provide an initial computer readable form (CRF) copy of the "Sequence Listing" and a statement that the content of the sequence listing information recorded in computer readable form is identical to the written (on paper or compact disc) sequence listing and, where applicable, includes no new matter, as required by 37 CFR 1.821(e), 1.821(f), 1.821(g), 1.825(b), or 1.825(d). If applicant desires the sequence listing in the instant application to be identical with that of another application on file in the U.S. Patent and Trademark Office, such request in accordance with 37 CFR 1.821(e) may be submitted in lieu of a new CRF.

- Total additional claim fee(s) for this application is $ **50**
  - **$50** for **2** total claims over 20.

Applicant is cautioned that correction of the above items may cause the specification and drawings page count to exceed 100 pages. If the specification and drawings exceed 100 pages, applicant will need to submit the required application size fee.

For questions regarding compliance to 37 CFR 1.821-1.825 requirements, please contact:

- **For Rules Interpretation, call (571) 272-0951**
- **For Patentin Software Program Help, call Patent EBC at 1-866-217-9197 or directly at 703-305-3028 / 703-308-6845 between the hours of 6 a.m. and 12 midnight, Monday through Friday, EST.**
- **Send e-mail correspondence for Patentin Software Program Help @ ebc@uspto.gov**

ALL OF THE ITEMS SET FORTH ABOVE MUST BE SUBMITTED WITHIN TWO (2) MONTHS FROM THE DATE OF THIS NOTICE OR BY 32 MONTHS FROM THE PRIORITY DATE FOR THE APPLICATION, WHICHEVER IS LATER. FAILURE TO PROPERLY RESPOND WILL RESULT IN ABANDONMENT.

The time period set above may be extended by filing a petition and fee for extension of time under the provisions of 37 CFR 1.136(a).

Applicant is reminded that any communications to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above (37 CFR 1.5)

*A copy of this notice **MUST** be returned with the response.*

SHELBY J VIGIL

Telephone: (703) 308-9140 EXT 224

PART 1 - ATTORNEY/APPLICANT COPY

U.S. APPLICATION NUMBER NO.	INTERNATIONAL APPLICATION NO.	ATTY. DOCKET NO.
10/552,660	PCT/SG04/00093	2577-158

FORM PCT/DO/EO/922 (371 Formalities Notice)

FORM PTO-1390 U.S. Department of Commerce Patent and Trademark Office

Attorney's Docket No. 2577-158

TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371

U.S. Application No. (if known) New Application

INTERNATIONAL APPLICATION NO.	INTERNATIONAL FILING DATE	PRIORITY DATE CLAIMED
PCT/US2004/000093	14 April 2004	14 April 2003

TITLE OF INVENTION
DETECTION OF TRANSGENES OF GENETICALLY MODIFIED ORGANISMS USING PYRO LUMINESCENCE

APPLICANT(S) FOR DO/EO/US
Yan HONG

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. [X] This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371

2. [ ] This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.

3. [X] This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below.

4. [X] The US has been elected (Article 31).

5. [X] A copy of the International Application as filed (35 U.S.C. 371(c)(2))
   a. [ ] is attached hereto (required only if not communicated by the International Bureau).
   b. [X] has been communicated by the International Bureau.
   c. [ ] is not required, as the application was filed in the United States Receiving Office (RO/US)

6. [ ] An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).
   a. [ ] is attached hereto.
   b. [ ] has been previously submitted under 35 U.S.C. 154(d)(4).

7. [X] Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))
   a. [ ] are attached hereto (required only if not communicated by the International Bureau).
   b. [X] have been communicated by the International Bureau.
   c. [ ] have not been made; however, the time limit for making such amendments has NOT expired.
   d. [ ] have not been made and will not be made.

8. [ ] An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).

9. [X] An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).

10. [ ] An English language translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

ITEMS 11. TO 20. below concern other document(s) or information included:

11. [ ] An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
12. [ ] An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
13. [X] A preliminary amendment.
14. [X] An Application Data Sheet under 37 CFR 1.76.
15. [X] A substitute specification.
16. [ ] A power of attorney and/or change of address letter.
17. [X] A computer-readable form of the sequence listing in accordance with PCT Rule 13*ter*.2 and 35 U.S.C. 1.821-1.825
18. [ ] A second copy of the published international application under 35 U.S.C. 154(d)(4).
19. [ ] A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).

U.S. APPLICATION NO. (If known) New Application	INTERNATIONAL APPLICATION NO. PCT/SG2004/000093	ATTORNEY DOCKET NO. 2577-158

20. [X] Other items or information:

[ ] RO/101 [ ] RO/105 [X] ISA/210(ISR) [ ] IB/301 [X] IB/304 [ ] IB/308 [ ] IB 401 [X] IB/409(IPER)

[X] IB/416 [X] Published Application WO/2004/090167 [X] ISA/237

21. The following fees are submitted:	CALCULATIONS	PTO USE ONLY
[X] Basic National Fee $300.00	$ 300.00	
22. [X] Examination Fee If the written opinion prepared by ISA/US or the IPER prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4) ..... $0 All other situations $200.00	$ 200.00	
23. [ ] Search Fee If the written opinion of the ISA/US or the IPER prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4) ..... $0 Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an International Search Authority ..... $100.00 International Search Report prepared by an ISA other than the US and provided to the Office or previously communicated to the US by the IB ..... $400.00 All other situations $500.00	$ 400.00	
TOTAL OF 21, 22 AND 23 =	$ 900.00	
[ ] Additional fee for specification and drawings filed in paper over 100 (excluding sequence listing or computer program listing filed in an electronic medium). The fee is $250.00 for each additional 50 sheets of paper or fraction thereof.	$	

Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof	Rate		
- 100 =	/ 50 =		x 250	$	
Surcharge of $130.00 for furnishing any of the search fee, examination fee, or the oath or declaration later than 30 months from the earliest claimed priority date (37 CFR 1.492(h)).				$	

Claims	Number Filed	Number Extra	Rate		
Total Claims	21 -20 =	1	X $50.00	$ 50.00	
Independent Claims	2 - 3 =		X $200.00	$	
Multiple dependent claim(s) (if applicable)			+ $360.00	$	
TOTAL OF ABOVE CALCULATIONS =				$	
[ ] Applicant claims small entity status. The fees indicated above are reduced by 1/2.				$	
SUBTOTAL =				$	
Processing fee of $130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(f)). +				$	
TOTAL NATIONAL FEE =				$	
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). $40.00 per property +				$	
TOTAL FEES ENCLOSED =				$ 950.00	
				Amount to be refunded	$
				Amount to be charged	$

U.S. APPLICATION NO. (If known) New Application	INTERNATIONAL APPLICATION NO. PCT/SG2004/000093	ATTORNEY DOCKET NO. 2577-158

a. ☐ A check in the amount of $_____ to cover the above fees is enclosed.

b. ☒ Please charge my Deposit Account No. 02-2135 in the amount of $ 950.00 to cover the above fees. A duplicate copy of this sheet is enclosed.

c. ☒ The Commissioner is hereby authorized to charge ***any additional fees*** which may be required, or credit any overpayment to Deposit Account No. 02-2135. A duplicate copy of this sheet is enclosed.

NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.

SEND ALL CORRESPONDENCE TO:

Customer No. 06449

Barbara Webb Walker
Rothwell, Figg, Ernst & Manbeck
1425 K St., N.W.
Washington, D.C. 20005
Phone: 202/783-6040

Barbara Webb Walker
Signature

Barbara Webb Walker
Name

35,400
Registration Number

2577-158.Form1390.wpd

PCT/SG2004/000093
Received 17 February 2005

CLAIMS

1. A method of identifying the presence of a transgene of a genetically modified organism in a sample wherein the nucleic acid of the transgene is replicated and detected as the release of pyrophosphate (PPi), the method comprising :

adding an oligonucleotide primer to the sample which hybridizes to the transgene;

subjecting the sample nucleic acid and primer to a polymerase reaction in the presence of a mixture of deoxynucleotides required for replication of the transgene whereby the deoxynucleotides are incorporated and release PPi proportional to the length of the DNA extension product; and

detecting any release of PPi enzymatically;

wherein release of PPi indicates the presence of the transgene.

2. The method of claim 1, wherein the transgene is replicated in a reaction selected from the group consisting of a polymerase extension reaction, a polymerase chain reaction (PCR), a ligase chain reaction (LCR), a rolling circle replication reaction (RCR) and a nucleic acid sequence based amplification reaction (NASBA).

3. The method of claim 2 wherein the transgene is replicated in a polymerase chain reaction.

4. The method of claim 1, wherein the release of PPi is detected by means of a Luciferase-Luciferin-based reaction.

5. The method of claim 1, wherein PPi release is detected using ATP sulfurylase and luciferase.

6. The method of claim 1, wherein the PPi detection enzymes are

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included in the polymerase reaction step and the polymerase reaction and PPi release detection steps are performed substantially simultaneously.

7. The method of claim 1, further comprising adding a dATP analogue which is capable of acting as a substrate for a polymerase, but incapable of acting as a substrate for a PPi detection enzyme.

8. The method of claim 7, wherein the dATP analogue is deoxyadenosine. alpha. thiotriphosphate.

9. The method of claim 1, wherein the sample DNA or oligonucleotide primer is immobilized or provided with means for attachment to a solid support.

10. The method of claim 1, for use with a multiplicity of sample DNA sequences, wherein said DNA sequences are arranged in assay format on a solid surface.

11. The method of claim 1, wherein said nucleic acid sample is from a plant.

12. The method of claim 11 wherein the plant is a food source.

13. A kit for detecting the presence of a transgene of a genetically modified organism in a sample as defined in claim 1, comprising:

a polymerase;

an enzyme detection means for identifying PPi release;

deoxynucleotides, or optionally deoxynucleotide analogues, optionally including, in place of dATP, a dATP analogue which is capable of acting as a substrate for a polymerase but incapable of acting as a substrate for a PPi-detection enzyme; and

optionally a transgene specific primer which hybridizes to the transgenic DNA and is recognized as a primer by a polymerase, wherein the polymerase replicates the transgenic DNA.

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14. The kit of claim 13, wherein the detection enzyme means comprises luciferin and luciferase.

15. The kit of claim 14, wherein the detection enzyme means comprises ATP sulfurylase and luciferase.

16. The kit of claim 13, wherein the transgene specific primer hybridizes to a transgene that provides herbicide resistance.

17. The kit of claim 16, wherein the transgene specific primer hybridizes to a transgene that provides resistance to the herbicides selected from glyphosate and glufosinate.

18. The kit of claim 13, wherein the transgene specific primer hybridizes to a transgene that provides insect resistance.

19. The kit of claim 13, wherein the transgene specific primer is selected from SEQ ID NOS. 1 to 29.

20. The method of claim 1, wherein the oligonucleotide primer is selected from SEQ ID NOS. 1-29.

21. A method of detecting a transgene of a genetically modified organism in a sample that may contain nucleic acid from the genetically modified organism wherein the nucleic acid of the transgene is replicated and detected as release of pyrophosphate, the method comprising:

adding an oligonucleotide primer selected from SEQ ID NOS. 1 to 29 to the sample;

subjecting the sample to a polymerase reaction; and

detecting the release of PPi;

wherein the release of PPi indicates the presence of a transgene in the sample.